

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as introduced, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report serious adverse drug events that they observe to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch.

By changing the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) The federal Food and Drug Administration (FDA) operates
4 a voluntary reporting system for adverse drug reactions known as
5 the MedWatch system.

6 (b) The FDA currently estimates that only 10 percent of the
7 adverse drug reactions or events that occur each year are reported
8 to the FDA.

9 (c) Given the prevalence of pharmaceuticals and their use for
10 treatment of hundreds of chronic diseases and conditions, and
11 given recent highly publicized instances of commonly used
12 prescription drugs being taken off the market due to safety
13 concerns that were discovered after the drugs were approved for
14 use, the systematic underreporting of adverse drug events
15 represents a serious public health problem.

16 (d) Requiring licensed health professionals of organizations to
17 report adverse drug events to the FDA would increase the
18 amount of data available to the FDA about adverse drug
19 reactions, thereby enabling the FDA to discern problems with
20 drugs that arise after they are approved and to take action to
21 protect the public health in a more timely manner.

22 SEC. 2. Article 7 (commencing with Section 111657) is
23 added to Chapter 6 of Part 5 of Division 104 of the Health and
24 Safety Code, to read:

25
26 Article 7. Adverse Event Reporting
27

28 111657. (a) A licensed health professional, including, but not
29 limited to, a physician and surgeon, dentist, or pharmacist, and a
30 health facility, including, but not limited to, a hospital or clinic,
31 shall report serious adverse drug events that they observe to
32 MedWatch, the drug safety information and adverse event
33 reporting program operated by the federal Food and Drug
34 Administration.

35 (b) For purposes of this section, serious adverse drug events
36 shall include adverse health outcomes involving patients that
37 result in death, life-threatening conditions, hospitalization,

1 disability, congenital anomaly, or required intervention to
2 prevent permanent impairment or damage.

3 (c) Any health professional or health facility that is required to
4 report an adverse drug event pursuant to this section shall do so
5 using the FDA 3500 Voluntary form developed by the federal
6 Food and Drug Administration for MedWatch.

7 SEC. 3. No reimbursement is required by this act pursuant to
8 Section 6 of Article XIII B of the California Constitution because
9 the only costs that may be incurred by a local agency or school
10 district will be incurred because this act creates a new crime or
11 infraction, eliminates a crime or infraction, or changes the
12 penalty for a crime or infraction, within the meaning of Section
13 17556 of the Government Code, or changes the definition of a
14 crime within the meaning of Section 6 of Article XIII B of the
15 California Constitution.